UNITED STATES PATENT AND TRADEMARK OFFICE

T.

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	37697-0033	8881

26633 7590 07/13/2007
HELLER EHRMAN LLP
1717 RHODE ISLAND AVE, NW
WASHINGTON, DC 20036-3001

EXAMINER	
BERMAN, SUSAN W	
ART UNIT	**PAPER NUMBER**
1711	
MAIL DATE	**DELIVERY MODE**
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/764,445	MERRILL, , EDWARD	
	Examiner	Art Unit	
	/Susan W. Berman/	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-130 and 143-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-130,143-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/07*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06-20-2007 has been entered.

Response to Amendment

The rejection of claims 124-130 and 143-149 under 35 U.S.C. 112, second paragraph, is withdrawn.

The rejection of claims 126-129 and 147-149 under 35 U.S.C. 102(e) as being anticipated by Salovey et al (6,281,264, having an effective filing date of 01/20/1995) is withdrawn. Salovey et al do not teach a method wherein the irradiated UHMWPE is heated. With respect to the product claims 126-129, applicant's arguments that the Rule 131 Declaration of Merrill et al shows reduction to practice of the method taught by Salovey et al before the 01/20/1995 filing date is persuasive of reduction to practice before 01-20-1995.

The rejection of claims 126-129 and 147-149 under 35 U.S.C. 102(e) as being anticipated by Shalaby et al (5,824,411) is withdrawn. Shalaby et al do not teach heating irradiated UHMWPE to a temperature above 150^0C or to melting.

Response to Arguments

Applicant's arguments filed 06-20-2007 have been fully considered but they are not persuasive with respect to the following issues.

The provisions of 35 USC 112, first and second paragraphs, require that claims be enabled by the disclosure of the invention in the specification and that claims clearly recite the features of the disclosed invention. In the situation wherein a specification discloses different embodiments of an invention, the claims should clearly describe the different embodiments and not confuse method steps for one embodiment with method steps for a different embodiment. The phrase "reading limitations of the specification into a claim" is concerned with interpreting a claim, as written, by 'reading" limitations described in the specification into the claim language when the claim language is broader than the description. In the instant case, claims were rejected because the claim language failed to clearly recite the method steps and/or order of steps defined in the embodiments of the invention as disclosed.

Applicant argues that the examiner is attempting to limit the claims in view of certain embodiments and not allowing steps that are "inherently disclosed" in the specification. The quoted passage defines the basis for amending an application to recite an inherent function, theory or advantage without introducing new matter. It is not agreed that this decision applies to omitting steps from method claims that were disclosed as being essential to the process for obtaining a product, as in the instant case. The different embodiments of the instantly disclosed invention, specifically "MIR" or "IR-SM", comprise different orders of melting and irradiation that would be expected to produce products having significantly different properties. In the absence of disclosure within the specification of method steps to be employed, it is not clear what steps could be considered to "inherent".

Applicant has filed a copy of the Rule 131 Declaration of Merrill et al originally filed 07/16/2004 in related application no. 10/197209 in order to show completion of the instantly

claimed invention prior to January 20, 1995. As stated in the response to the Declaration mailed 12/20/2004 (in SN 10/1979,209), The data in the Declaration is considered to clearly show reduction to practice of the disclosed "MIR" process before January 20, 1995. No evidence of reduction to practice of the instantly claimed embodiment wherein irradiation is followed by melting, i.e. "IR-SM", before January 20, 1995 was noted. The evidence in the Declaration shows that DSC thermal analysis involved melting irradiated UHMWPE to measure the % crystallization of the treated polyethylene. As stated in the Declaration this "DSC method is used to determine melting and crystallization temperatures as well as the energy input required to melt and energy output generated during crystallization" (page 5, paragraph 13). That the thermal analysis involved melting irradiated UHMWPE to obtain the desired data does not provide evidence of a concept of or a reduction to practice of treatment by irradiation and subsequent or adiabatic melting of the irradiated material in order to obtain a desired implant before January 20, 1995. DSC is routinely used for such measurements. Furthermore, DSC is not mentioned in the instant specification as being used to provide the subsequent melting step in the "IR-SM" method disclosed in 08/726313. A method of irradiation followed by melting or by "DSC" measurements was not mentioned in application no 08/600744. The "IR-SM" embodiment is first mentioned in application number 08/726313, filed 10/02/1996.

Applicant's arguments with respect to effective filing date being 02-13-1996 for "IR-SM" embodiments are unpersuasive for the reasons set forth above and previously of record.

Shen et al: Applicant argues that US '900 does not qualify as prior art because applicant's initial filing date 02-13-1996 for SN 08/600744 is before Shen et al's earliest filing date of 07-09-1996. This argument is not persuasive because applicant's effective filing date with respect to

the rejected claims is the 10-02-1996 filing date of SN 08/726313. As discussed above and in previous office actions in detail, SN 08/600,744 discloses "MIR" and does not disclose "IR-SM" methods. Shen et al clearly disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing in US '900 and in provisional application 60/017852, filed 07-09-1996. The disclosure of Shen et al '900 anticipates applicant's methods and products, as claimed, because the claimed method has an effective filing date of 10-02-1996. Applicant's claims do not recite the "MIR" method disclosed in SN 08/600,744, filed 02/13/1996, as discussed above.

Hyon et al: Applicant argues that Hyon et al (6,168,626, having an effective filing date of May 6, 1996) is antedated by applicant's initial filing. This argument is unpersuasive because Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. It is noted that the Hyon et al filing date of 05/06/1996 is before applicant's 10/02/1996 disclosure of the claimed method comprising irradiating UHMWPE and subsequently melting the irradiated UHMWPE.

Claim Interpretation and Effective Filing Date

Claims 124-130 and 143-149, as amended, recite the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313, filed 10-02-1996. Thus, claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of 10/02/1996 with respect to prior art disclosures. The instant claims are considered to be fully

supported by the disclosure of SN 08/726,313, but not by SN 08/600744 filed 02-13-1996, wherein a method of irradiating UHMWPE in the molten state is disclosed but subsequent melting after irradiation is not taught. Therefore, the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the 10/02/1996 filing date of SN 08/726,313.

Furthermore, claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN '744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN '744. SN '313 does disclose the swell ratio or degree of oxidation of the disclosed UHMWPE, therefor, the effective filing date for claims 128-129 is considered to be 10/02/1996.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124-125, 128, 130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claims 124, 125, 130, the recitation "temperature above about 150^0C" renders the claims indefinite. If applicant intends to claim a temperature "above 150^0C", it should be so stated. If applicant intends to claim a temperature "about 150^0C", it should be so stated. With respect to claim 128, the recitations "less than about 5" and "between about 20 μm to about 3 mm" render the claim indefinite. If applicant intends to claim "less than 5", it should be so stated. If applicant intends to claim "about 5", it should be

so stated. If applicant intends to claim "depth between...", it should be so stated. If applicant intends to claim "depth from about ...", it should be so stated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996). Applicant's effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (effective filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129.

Claims 125-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded

article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and 127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reasons are that Hyon et al disclose the process steps set forth in claim 125 and 128 and the process steps in claim 124 except for sterilizing the implant and that the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims.

It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 126-127 and 135-136 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in

the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '089 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124,125,129,130,132-134,136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
7/5/2007

/Susan W Berman/
Primary Examiner
Art Unit 1711